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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/319,736	08/02/99	WOLPERT E	000500-182

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BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA VA 22313-1404

EXAMINER	
LACOURCIERE,K	
ART UNIT	**PAPER NUMBER**
1635	15

DATE MAILED: 08/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/319,736	Applicant(s) WOLPERT ET AL.
	Examiner Karen A. Lacourciere	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-53,55-63 and 65-142* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *13-53,55-63 and 65-142* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant has received an examination of the instant case (see Office action mailed 3-15-00), however, in response to amendments filed on 09-18-00 and 06-06-01, a lack of unity is required in this case. This is in response to Applicant filing an excessive number of new claims and claims which have been amended to such an extent that the burden of examining multiple inventions in this case has become too large for the examiner. Because Applicant has already recieved an examination in this case, Applicant is required to elect an invention which was examined as part of the original examination of the instant case.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 13-22, 23, 24, 115, 116, 117 and 132-133, drawn to an isolated antigen or epitope, a method of making said antigen or epitope and a method of using said antigen or epitope.

Group II, claim(s) 25 and 26, drawn to a nucleic acid encoding an antigen or epitope.

Group III, claim(s)26 and 27, drawn to a method of preparing a pharmaceutical composition comprising a nucleic acid encoding an antigen or epitope.

Group IV, claim(s)28 and 29, drawn to a method of treatment using a pharmaceutical composition comprising a nucleic acid encoding an antigen or epitope.

Group V, claim(s)30-32, drawn to a method of eliciting or stimulating immunological effector cells by contacting effector cells with antigens or epitopes .

Group VI, claim(s) 33-47, drawn to a method of preparing a pharmaceutical agent or vaccine.

Group VII, claim(s) 48-57, drawn to a method of treatment by administering cells to a patient.

Group VIII, claim(s) 58-63 and 117-123, drawn to a method of treatment comprising removal and treatment of cells from a patient.

Group IX, claim(s) 65-68 and 134-137, drawn to a pharmaceutical composition comprising an agent that inhibits cellular peptide processing for MHC presentation.

Group X, claim(s) 65-70, 138 and 139, drawn to a nucleotide sequence encoding an agent that inhibits cellular peptide processing.

Group XI, claim(s) 65-68, 71-73 and 140-142, drawn to a nucleotide sequence complementary to a sequence encoding a component that takes part in cellular peptide processing.

Group XII, claim(s) 74, 76 and 77, drawn to a method of treatment using a pharmaceutical composition comprising an agent that inhibits cellular peptide processing for MHC presentation.

Group XIII, claim(s) 74-79, 124, drawn to a method of treatment using a nucleotide sequence encoding an agent that inhibits cellular peptide processing.

Group XIV, claim(s) 74-77, 80-82, and 125-127, drawn to a method of treatment using a nucleotide sequence complementary to a sequence encoding a component that takes part in cellular peptide processing.

Group XV, claim(s) 83-104, drawn to a method of eliciting or stimulating effector cells by contacting effector cells with cells expressing antigens or epitopes .

Group XVI, claim(s) 105-110 and 129-131, drawn to a pharmaceutical composition comprising cells specific for antigens or epitopes.

Group XVII, claim(s) 111, drawn to a method of making a pharmaceutical composition comprising cells specific for antigens or epitopes.

Group XVIII, claim(s) 112 and 113, drawn to a pharmaceutical composition comprising cells expressing endogenous antigens or epitopes associated with impaired cellular peptide processing.

Group XIX, claim(s) 114, drawn to a method of making a pharmaceutical composition comprising cells expressing endogenous antigens or epitopes associated with impaired cellular peptide processing.

Group XX, claim(s) 128, drawn to a method of inducing expression of antigens or epitopes in cells.

2. The inventions listed as Groups I-XXI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Sanda et al. (reference cited by Applicant on PTO form 1449, filed 09-18-01) disclose antigens or eptiopes associated with impaired cellular processing expressed on target cells expressing beta-2-microglobulin. Therefore, the subject matter of claim 13 is not free of the prior art and as such, a special technical feature does not link the claims of the instant application. Further, under 37 CFR 1.475 (b) Applicant is entitled to the first product, a method of making said product and a method of using said product.

3. Group I is drawn to a first product, an isolated antigen or epitope associated with impaired cellular processing, a method of making said product and a method of treatment using said product. The products of Group II, IX, X, XI, XVI, and XVIII are each drawn to products which differ from the product of Group I and from each other by being materially different products. For example, the nucleic acid sequences of Groups II, X, XI are composed of nucleotides and differ materially from the epitopes of Group I, which are composed of amino acids. The nucleic acid sequences of Groups II, X, and XI each encode different biological products and, therefore, are different inventions. The product of Group IX is drawn to agents

which inhibit cellular peptide processing, and differs from the epitopes of Group I, which are expressed in response to impaired cellular processing , and differ materially from the nucleic acids of each of Groups II, X, and XI, and which have a different biological function, to encode a protein, than the function of the agents of Group IX. The products of Groups XVI and XVIII are each drawn to cells, which are materially different than the epitopes of Group I. The cells of Group XVI are specific for antigens and epitopes which differ from the cells of Group XVIII, which express endogenous epitopes, and each of Groups II, X, IX and XI.

Each of the methods of Groups III, VI, XVII, XIX are drawn to methods of making pharmaceutical compositions, which are a different class of invention than the products of each of Groups I, II, X, IX, XVI and XVIII. The methods of Groups III, VI XVII and XIX comprise materially different method steps, which result in materially different products.

Each of the methods of Groups IV, VII, VIII, XII, XIII and XVI are drawn to a method of treatment, which is a different class of invention than the products of each of Groups I, II, X, IX, XVI and XVIII. The treatment methods of Groups IV, VII, VIII, XII, XIII and XVI comprise materially different method steps than each of the methods of preparing pharmaceutical compositions of Groups III, VI XVII and XIX and have a different biological outcome than said methods. The methods of Groups IV, VII, VIII, XII, XIII and XVI are different from each other in that they each comprise materially different steps and each utilize a materially different composition.

The methods of Groups V and XV are drawn to methods of eliciting or stimulating effector cells, which is a different class of invention than the products of each of Groups I, II, X, IX, XVI and XVIII. The methods of each of Groups V and XV result in stimulation of effector cells and comprise different method steps than each of the methods of preparing pharmaceutical compositions of Groups III, VI XVII and XIX and treatment methods of Groups IV, VII, VIII, XII, XIII and XVI have a different biological outcome than said methods. The methods of Groups V and XV differ from each other in that the methods of Group V comprise the step of contacting effector cells with epitopes or antigens directly, whereas the methods of Group XV comprise the step of contacting effector cells with cells which express epitopes or antigens.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is reminded that the invention elected must be an invention examined as part of the original examination of the instant case.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at (703) 308-0447. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SEAN McGARRY
PRIMARY EXAMINER

Karen A. Lacourciere

August 12, 2001